Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510-337-6700

Via Federal Express

Our Reference 29-52451

March 25, 1999

Filip C. Lima
Joseph A. Lima
Lima Brothers Dairy
5217 West Oak Avenue
Merced, California 95340

WARNING LETTER

Dear Messrs. Lima:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on March 3 and 4, 1999, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon has revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On December 24, 1998, you sold a calf (identified by USDA laboratory report number 391496) for slaughter as human food. This calf was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this calf revealed streptomycin in the kidney at 3.00 parts per million (ppm) and in the liver at 8.80 ppm. Presently, the tolerance level for streptomycin in the uncooked edible tissues of calves is 2.00 ppm in the kidney and 0.5 ppm in other tissues. The USDA analysis also revealed sulfamethoxazole in the liver at 0.14 ppm. Presently, there is no tolerance level for sulfamethoxazole in the uncooked edible tissues of cattle.

Spectinomycin, sold as Spectam Scour-Halt, is commonly reported by the USDA Lab as streptomycin. Spectinomycin and streptomycin are in the same class of drugs, and USDA will often report the drug with the highest tolerance in that class of drugs. The calf you delivered for slaughter had illegal residues of streptomycin, as reported by USDA, but the residue was spectinomycin (Spectam Scour-Halt)

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

4. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.

5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

The drug Spectam Scour-Halt brand of spectinomycin that you use to treat your calves is adulterated under Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v) and unsafe within the meaning of Section 512 (a)(1)(B) of the Act since it is not being used in conformance with approved labeling. Labeling for Spectam Scour-Halt specifically states it is for use in pigs under four weeks of age and prescribes a twenty-one day withdrawal time. Your practice of administering spectinomycin to calves is not in conformance with approved labeling. Treatment of a calf with spectinomycin is likely the cause of the illegal residues found in the calf you sold for food use.

Your use of the drug AGRI-CILLIN brand penicillin G procaine is not in conformance with its approved labeling directions. Labeling for AGRI-CILLIN prescribes a dosage of 1 milliliter (ml) per 100 pounds of body weight and warns against injecting more than10 mls into one site. Your practice of administering 25 mls of penicillin per injection site, twice a day, in your dairy cows results in a dosage in excess of that allowed by the labeling.

Failure to comply with the label instructions on a drug presents the likely possibility that illegal residues will occur and makes the drug unsafe for use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered for human food use where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering cull cows and calves for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of March 10, 1989, through December 24, 1998, your firm offered six calves for food use which were found to contain illegal drug residues. During this same period you sold eleven calves which were found to be CAST or FAST positive due to the possible presence of harmful levels of antibiotics. An inspection was conducted of your dairy on March 13, 1996. During the inspection you were warned that it is illegal to market animals with illegal levels of antibiotics. A Warning Letter, dated April 18, 1996, was sent to you as a result of the violations found during the inspection. Also, USDA sent you a letter for each instance in which their analysis found violative levels of drug residues. You have failed to take corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify our Fresno resident post office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Thomas W. Gordon, Investigator, Food and Drug Administration, 2202 Monterey Avenue, Suite 104E, Fresno, California 93721.

Sincerely yours,

Patricia Ziobro

Patricia Ziobro
District Director
San Francisco District

cc: [redacted]